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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,041	02/09/2001	Ronald Klein	UF-10293	8442

29847 7590 09/27/2005

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ORLANDO, FL 32801

EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/780,041

Applicant(s)

KLEIN ET AL.

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23,27,28,30,31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23,27 and 28 is/are allowed.
- 6) ☒ Claim(s) 30,31 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The amendment filed June 27, 2005 has been entered. Claims 23 and 30 have been amended. Claims 24-26, 32, 34, 35, and 39-41 have been cancelled. The remarks filed November 18, 2004 (hereinafter referred to as "the response") are considered herein.

Accordingly, Claims 23, 27, 28, 30, 31, and 33 are pending in the instant application.

The objection to the drawings is withdrawn in view of the replacement drawing filed November 18, 2004.

The objection to Claim 32 is withdrawn in view of the cancellation of the claim.

The rejection of Claims 34 and 35 under 35 U.S.C. 101 is withdrawn in view of the cancellation of these claims.

The rejection of Claims 23, 27, and 28 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn in view of the amendments to Claim 23.

The rejection of Claims 23, 27, and 28 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of the amendments to Claim 23.

The rejection of Claims 30-33 and 40 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendments to Claim 30, the arguments presented at page 7 of the response, and the cancellation of Claims 32 and 40.

The rejection of Claims 34 and 35 under 35 U.S.C. 102(a) as being anticipated by Gotz et al. (2001) is withdrawn in view of the cancellation of these claims.

The rejection of Claims 34 and 35 under 35 U.S.C. 102(a) as being anticipated by Lewis et al. (2000) is withdrawn in view of the cancellation of these claims.

***Enablement***

Claims 30 and 31 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record, because the specification, while being enabling for a method for inducing behavioral changes in a mouse or rat by administration of a viral vector encoding a mutant form of human tau comprising the P301L mutation, does not reasonably provide enablement for the broad scope of methods for producing rats and mice by transferring a gene encoding an aberrant form of tau protein comprising the P301L mutation associated with FTDP-17 as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims remain broader than the indicated scope of enablement and no arguments have been provided for using vectors other than viral vectors. See the scope of enablement set forth at page 6 of the Office Action mailed June 15, 2004. As presently claimed, the claims cover the use of naked DNA, as well as all types of vectors encoding the aberrant form of tau protein recited in the claims, but the specification only enables the use of viral vectors for producing the phenotypes disclosed in the specification, for reasons of record.

***Allowable Subject Matter***

Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Claims 23, 27, and 28 are allowable.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*

**ANNE-MARIE FALK, PH.D**  
**PRIMARY EXAMINER**